Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

14 August 2023

Dear [redacted]

FOI 23/382

Thank you for your Freedom of Information (FOI) request dated 24 May 2023 in which you requested all raw, case-specific data submitted to the Yellow Card Scheme from the Isle of Man, for the period January 2021 to date, concerning the available COVID-19 vaccines. Please accept our apologies for the delay in our response, MHRA have been awaiting feedback following discussions with DHSC.

The information you have requested within FOI 23/382 is exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI act. Supplying you with this information could lead to patient or reporter identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy[1], the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

As part of our proactive vigilance surrounding the COVID-19 vaccines, the MHRA collects reports of suspected side effects via the Yellow Card scheme. The Yellow Card scheme underpins medicines and vaccines safety monitoring in the UK. Through this scheme, members of the public and healthcare professionals voluntarily submit reports of suspected side effects to the MHRA. The key strength of the Yellow Card scheme is that it allows any member of the public or health professional across the UK to immediately alert us to any concerns they have without a formal diagnosis. As such, Yellow Card reports are constantly reviewed and may contribute to the identification of a potential safety signal.

The Agency Yellow Card Privacy Policy[1] states that:

"We do not share your identity with any person outside the MHRA without your explicit consent unless we are required or permitted to do so by law. Examples include if we receive a court order to do so or if you are a healthcare professional reporting an adverse incident relating to a medical device, further details of which can be found below. Exceptionally, we may share this where we have established a lawful basis for sharing personal data and can demonstrate that it is both necessary and proportionate to do so.

We may receive requests for Yellow Card report data under the Freedom of Information Act. While we are legally obliged to provide some of the requested information, we only provide high-level summary information with all person-identifiable data excluded." (my emphasis).

Our lawful basis for processing personal data is General Data Protection Regulation (GDPR) Article 6(1)(e), which allows us to process personal data when this is necessary to perform our public tasks as a regulator.

The lawful bases we rely on to process special category personal data are Article 9(2)(i) of the GDPR and Schedule 1 part 1(3) of the DPA, both of which enable us to process such information when it is necessary for reasons of the public interest in the area of public health.

Where we share Yellow Card data for scientific or public health research purposes, we rely on GDPR Article 9(2)(j) as our lawful basis for processing special category personal data and Schedule 1 part 1(4) of the DPA. These bases permit us to process personal data for these purposes where it is in the public interest, subject to appropriate safeguards to protect the reporter/patient's rights and freedoms. We consider that the information requested, taken as a whole, meets that threshold for special category personal data and are considered to be submitted to the MHRA in confidence. The above information is outlined in our Privacy Policy[1].

Whether or not all or any of this data is special category data, we cannot rely on legal obligation to disclose it, other than on the basis of consent or legitimate public health interests. The ICO guidance[2] relied upon here for Section 40 states that:

Although you have a legal obligation to respond to an FOI or EIR request, the test for the exemption is whether disclosure 'otherwise than under' these laws would contravene the data protection principles. Therefore, you cannot argue that the legal obligation basis at 6(1)(c) justifies disclosure under FOIA or the EIR.

It is also relevant to note here in respect of Section 40 and Section 41:

1. ***Unauthorised disclosure would cause a specific detriment to either the party which provided it or any other party; and***
2. ***Although Section 41 is an absolute exemption, the law of confidence contains its own built in public interest test with one defence to an action being that disclosure is in the public interest.***

[1] https://coronavirus-yellowcard.mhra.gov.uk/privacy-policy

[2] https://ico.org.uk/media/for-organisations/documents/1213/personal-information-section-40-regulation-13.pdf

Detriment may be assumed where the information concerns the individual's personal or private life, which we consider this information does. Notwithstanding, we consider that disclosure of this information would not be in the public interest for the following reasons.

The MHRA has been working proactively to encourage members of the public or health professionals across the UK to immediately alert us to any concerns they have without a formal diagnosis using the Yellow Card scheme. The information and data provided to us by these third parties are shared in confidence and, as above, are personal data. Sharing the information and data received with the enquirer would not reflect the commitments in MHRA's confidentiality agreements which would be of detriment both to the application of the Agency's regulatory function and public health more widely. As this is personal data in relation to an individuals' medical information, this would be of detriment to them and may damage the engagement with the scheme.

We have carefully considered whether the law of confidence would be breached, and whether, notwithstanding this, there is sufficient public interest in disclosure. We consider that disclosure of this information is not in the public interest and, therefore, do not consider any such breach defensible. Yellow Card reports are constantly reviewed and may contribute to the identification of the individual submitting the report or to whom the report is about.

As you have seen from previous published FOI responses, we would be able to provide you with data submitted to the Yellow Card Scheme from the Isle of Man concerning the COVID-19 vaccines that maintains patient and reporter confidentiality if you wish to make another request. We can provide you with a breakdown of the total number of suspected Adverse Drug Reaction (ADR) reports from the Isle of Man for each of the COVID-19 vaccines. We can also provide further breakdowns of this data using the data fields displayed on our COVID-19 vaccine interactive Drug Analysis Profiles (iDAPs)[3], such as patient age group or patient sex. However, please note that where there are less than 5 reports for a particular subgroup, numbers will always be replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters.

Yellow Card data is only a small part of the information utilised as part of our proactive vigilance surrounding the COVID-19 vaccines[4] and as you are aware from interactions with DHSC, Yellow Card data cannot be used in isolation to take deployment decisions. We recommend that you engage with DHSC to understand the wider data sources that are used to determine deployment decisions, that are outside of the remit of the MHRA.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

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[3] https://yellowcard.mhra.gov.uk/idaps

[4] https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance

Medicines and Healthcare products Regulatory Agency

If you have a query about this email, please contact us.

If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF